DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 21, 2015

Microlife Intellectual Property GmbH
c/o Susan D. Goldstein-Falk
MDI Consultants, Inc.
55 Northern Blvd. Ste 200
Great Neck, NY 11021

Re: K143341
Trade/Device Name: ProBP 2400 Digital Blood Pressure Device
Regulation Number: 21 CFR 870.1130
Regulation Name: Non-Invasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: March 12, 2015
Received: March 13, 2015

Dear Ms. Goldstein-Falk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

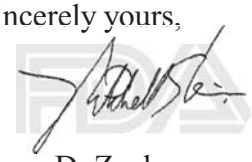
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143341

Device Name
ProBP 2400 Digital Blood Pressure Device

Indications for Use *(Describe)*
The ProBP 2400 is a non-invasive digital blood pressure device using oscillometric technique and an upper-arm blood pressure cuff to measure systolic and diastolic blood pressures, pulse rate and mean arterial pressure (MAP).

The device detects the appearance of irregular heartbeat during measurement, and gives a warning signal with the reading once the irregular heartbeat is detected.

The device can accurately measure blood pressure in pregnant patients including those with known or suspected pre-eclampsia.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY

The assigned 5l0(k) number is: K143341

1. Submitter's Identification:

Microlife Intellectual Property GmbH, Switzerland
Espenstrasse 139
9443 Widnau / Switzerland

Date Summary Prepared: April 10, 2015

Contact: Mr. Gerhard Frick
Vice President of Technical and Service
Microlife Intellectual Property GmbH, Switzerland
Tel: +41 79 216 0070
E-Mail: gerhard.frick@microlife.ch

2. Name of the Device:

ProBP 2400 Digital Blood Pressure Device

Regulation Number: 21 CFR Part 870.1130
Regulation Name: Non-Invasive Blood Pressure Measurement System
Regulatory Class: II
Product Code:
DXN

3. Information for the 510(k) Cleared Device (Predicate Device):

a. Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model WatchBP Office Afib(TWIN200 AFS), K101275, Microlife Intellectual Property GmbH.

b. Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model BP3MW1-4X(R), K140572, Microlife Intellectual Property GmbH.

4. Device Description:

ProBP 2400 Digital Blood Pressure Device is designed to measure systolic and diastolic blood pressure, pulse rate and mean arterial pressure (MAP) of an individual by using a non-invasive technique in which one inflatable cuff is wrapped around the single upper arm. Our method to define systolic and diastolic pressure is similar to the auscultatory method but use two resistive pressure sensors rather than a stethoscope and mercury manometer. The sensors convert tiny alterations in cuff pressure to electrical signals, by analyzing those signals to define the systolic and diastolic blood pressure and calculating pulse rate, which is a well - known technique in the market called the “oscillometric method”.

The device can accurately measure blood pressure in pregnant patients including those with known or suspected pre-eclampsia.

The device has 1x, 3x, and MANUAL measurement modes and has irregular heartbeat detection function, inflation pressure setting function, measurement intervals setting function etc.

The 1x mode is selected to perform single blood pressure measurement of patients.

The 3x mode is selected to complete a fully-automated triple measurements. Taking fewer than three measurements can be stopped by pressing the Start/Stop button.

The MANUAL mode is selected for blood pressure measurement of patients to confirm if a patient is suitable for the oscillometric method.

5. Intended Use:

The ProBP 2400 is a non-invasive digital blood pressure device using oscillometric Technique and an upper-arm blood pressure cuff to measure systolic and diastolic blood pressures, pulse rate and mean arterial pressure (MAP).

The device detects the appearance of irregular heartbeat during measurement, and gives a warning signal with the reading once the irregular heartbeat is detected.

The device can accurately measure blood pressure in pregnant patients including those with known or suspected pre-eclampsia.

6. Comparison to the 510(k) Cleared Device (Predicate Device):

The modified device model ProBP 2400 and the predicate device model WatchBP Office Afib(TWIN200 AFS) use the well-known oscillometric method within the software algorithm to determine the systolic and diastolic blood pressure and pulse rate. Upper arm cuff is inflated automatically, deflation rate is controlled by one factory set exhaust valve and the deflation pressures are transferred via tubing to one sensor.

They differ by the intended use, early preeclampsia detection function, dual-arm must be measured simultaneously in SCREEN mode, measurement modes name.

Although the modified device ProBP 2400 is validated for preeclampsia, which is the same as with the BP3MW1-4X(R), the subject device, ProBP 2400 does not have the screen mode, which must be measured dual-arm simultaneously, and has a 1x mode, 3x mode, and manual mode which is the same as with the AUSCULTATION MODE of TWIN200 AFS. The differences do not affect the accuracy and normal use of this device because they use the same fundamental scientific technology based on clinical declaration of identity.

The modified device model ProBP 2400 uses the same oscillometric method as the predicate device BP3MW1-4X(R). They have the same IHD function and are validated in preeclampsia. Based upon the aforementioned information, the two devices are substantially equivalent.

7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Testing information demonstrating safety and effectiveness of the Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model ProBP 2400 in the intended environment of use is supported by testing that was conducted in accordance with the FDA November 1993 Draft "Reviewer Guidance for Premarket Notification Submissions", DCRND, which outlines Electrical, Mechanical and Environmental Performance requirements.

The following testing was conducted to prove safety and effectiveness as well as substantial equivalence to the predicate devices:

Reliability testing that included storage testing, operating testing, vibration testing, drop testing and life testing was conducted to verify that the subject device functions meet required specifications.

The following National and International Standards were utilized for testing the subject device:

1) IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance 1988 A1:1991 A21995

2) IEC 60601-1-2 Medical electrical equipment Part 1-2: General requirements for safety and essential performance – Collateral standard: Electromagnetic compatibility 3:2007-03

3) AAMI/ANSI SP10 Manual, electronic, or automated sphygmomanometers 2002 (R) 2008, 2002 A1:2003

4) EN 1060-1 Non-invasive sphygmomanometers Part 1: General requirements
1995: Amendment 2, 2009

5) EN 1060-3 Non-invasive sphygmomanometers Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems. 1997: Amendment 2, 2009

6) ISO 14971 Medical devices – Application of risk management o medical devices. 2007

7) AAMI/ANSI/ISO 10993-1-1 Biological evaluation of medical devices – Part 1: Evaluation and testing. 2010

8) AAMI/ANSI/ISO 10993-5 Biological evaluation of medical devices – Part 5: Tests for In Vitro Cytotoxicity, 2009

9) AAMI/ANSI/ISO 10993-10 Biological evaluation of medical devices – Part 10: Tests for Irritation and skin sensitization, 2010

10) AAMI/ANSI/IEC 80601-2-30 Medical electrical equipment – Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers, 2013

None of the testing demonstrated any design characteristics that violated the requirements of the Reviewer Guidance or resulted in any safety hazards. It was our conclusion that the BP 2400 Digital Blood Pressure Device tested met all relevant requirements of the aforementioned tests.

8. Discussion of Clinical Tests Performed:

a) Clinical Validation Concerning the Compliance of ANSI/AAMI ISO 81060-2: The subject modified device, Model ProBP 2400, is from the technical point of view, identical to our predicate device Model WatchBP Office Afib(TWIN200 AFS). Moreover, the measurement algorithm of WatchBP Office Afib(TWIN200 AFS) remain unchanged. The fundamental scientific technology of the modified WatchBP Office Afib(TWIN200 AFS) device is the same as the predicate device ProBP 2400. Therefore the performance of the ProBP 2400 in terms of blood pressure measurement would be identical with performance of the predicate device WatchBP Office Afib(TWIN200 AFS). Repeat clinical testing in accordance with the standard ANSI/AAMI IEC 81060-2 for the subject device ProBP 2400 is therefore not necessary as clinical testing results were not affected by the changes to the subject modified device.

b) Clinical validation concerning detection for women in pregnancy and pre-eclampsia:

The accuracy measurement in pregnancy and pre-eclamplsia utilized in the subject modified device Model ProBP 2400 is from the technical point of view, identical to what is utilized in our predicate device Model BP3MW1-4X(R). The clinical test report of BP3MW1-4X(R), K140572 in pregnancy and preeclampsia, is applicable to our subject modified ProBP 2400.

9. Software information:

Software validation was conducted in accordance with a moderate level of concern designation in accordance with the FDA November 2005 document “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices”. In addition, since our device requires the use of off-the-shelf software to operate the PC-link function, we adhered to the FDA September 1999 document “Guidance for Off-The-Shelf Software Use in Medical Devices”.

10. Conclusions:

Conclusions drawn from the non-clinical and clinical tests demonstrate that the subject device is as safe, effective, and performs as well as the predicate device.